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# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

All Actions

Lead Case No. 3:21-cv-03825-VC

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CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

**JURY TRIAL DEMANDED** 

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Plaintiffs Larkin Community Hospital, Franciscan Alliance, Inc., King County Public Hospital District No. 1, DBA Valley Medical Center, and Kaleida Health (collectively, "Plaintiffs"), on behalf of themselves and all others similarly situated, upon knowledge with respect to their own actions and upon information and belief with respect to all other matters, allege by way of Complaint against Defendant Intuitive Surgical, Inc. ("Intuitive"):

#### INTRODUCTION

- 1. Intuitive dominates the market for minimally invasive surgical robots with its da Vinci robots ("da Vinci"). Intuitive's dominance in this market is so complete that for over a decade Intuitive faced *no competition whatsoever*. Even now, Intuitive maintains a market share of at least 98%. Through anticompetitive conduct, Intuitive abuses its dominance to limit competition two separate markets: (1) the aftermarket for da Vinci service; and (2) the aftermarket for the replacement and repair of EndoWrists, i.e., the costly, limited-use surgical instruments (such as graspers, forceps, and scissors) required to perform surgery with a da Vinci.
- 2. Intuitive has been engaged in an anticompetitive scheme pursuant to which it ties the purchase or lease of the da Vinci to, and otherwise conditions the purchase or lease of the da Vinci on, the purchase from Intuitive of service of the da Vinci and the repair and replacement of EndoWrists—a violation of Sections 1 and 2 of the Sherman Act.
- 3. Intuitive conditions the purchase or lease of a da Vinci on acceptance of Intuitive's service contract. The service contract requires the purchaser to use Intuitive as the sole service provider for all da Vincis and prohibits the purchaser from either servicing the robot itself or hiring an independent repair company ("IRC") to service the da Vinci.
- 4. Intuitive also ties the purchase or lease of a da Vinci to the purchase of replacement EndoWrists from Intuitive. Both contractually and technologically, Intuitive

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restricts the number of times a purchaser may use the EndoWrists, in most cases to a mere ten uses—without any medical justification. The sole purpose of artificially suppressing the number of EndoWrist uses is to artificially inflate the number of EndoWrists hospitals must purchase to perform life-saving surgeries. Moreover, according to the terms of the agreements Intuitive requires for the purchase or lease of the da Vinci ("Sales Agreements"), hospitals cannot hire IRCs to service or repair their EndoWrists (e.g., clean or sharpen them for longer use). These restrictions cause Plaintiffs and proposed Class members (defined in paragraph 163, infra; hereinafter, the "Class")) to purchase at supracompetitive prices substantially more EndoWrists

5. Intuitive's conduct with regard to both da Vinci service and EndoWrist repair and replacement is precisely the type of anticompetitive behavior the Federal Trade Commission ("FTC") condemned in a July 2021 Policy Statement, in which the FTC explained that as part of its "Nixing the Fix" workshop, "the Commission uncovered evidence that manufacturers and sellers may, without reasonable justification, be restricting competition for repair services in numerous ways, including . . . limiting the availability of parts, manuals, diagnostic software, and tools . . . disparaging non-OEM parts and independent repair; using unjustified software locks . . . and imposing restrictive end use license agreements." The FTC specifically noted that "certain repair restrictions may constitute tying arrangements or monopolistic practices—such as refusals to deal, exclusive dealing, or exclusionary design—that violate the Sherman Act."<sup>2</sup>

<sup>1</sup> Policy Statement of the Federal Trade Commission on Repair Restrictions Imposed by Manufacturers and Sellers (July 21, 2021), at 1, available at https://www.ftc.gov/system/files/documents/public statements/1592330/p194400repairrestrictio nspolicystatement.pdf (last visited on September 10, 2021).

than necessary.

<sup>&</sup>lt;sup>2</sup> *Id.* at 2.

- 6. There is a relevant primary market for minimally invasive surgical robots, and relevant aftermarkets for the (a) service of da Vinci robots and (b) repair and replacement of EndoWrists, which are separate from the primary market and from each other. Intuitive has monopoly power in every relevant primary market and aftermarket. Intuitive illegally exploits its market power in the minimally invasive surgical robot market to foreclose competition in the aftermarkets for da Vinci service and the repair and replacement of EndoWrists. The scheme is highly successful and has almost completely inhibited competition in those aftermarkets, precluding customers from using IRCs, which deliver the same quality service at lower prices. Intuitive's conduct has thereby significantly increased costs to Plaintiffs and the Class. For example, IRCs Restore Robotics LLC ("Restore"), Surgical Instrument Service Company, Inc. ("SIS"), Revanix Biomedical ("Revanix"), and Rebotix Repair LLC ("Rebotix") offer repair services for EndoWrists by skilled and experienced technicians and Restore likewise services the da Vinci itself. Other companies are in the business of servicing and repairing medical equipment and/or surgical instruments and would likely enter the aftermarkets for servicing of da Vinci robots and/or repairing and replacing EndoWrists but for Intuitive's anticompetitive conduct.
- 7. Defendant's anticompetitive scheme drives the majority of its annual revenues: in 2019, 57% of Intuitive's U.S. revenue was attributable to instrument and accessory sales and replacement, and 16% was attributable to service contracts.
- 8. But for Intuitive's anticompetitive scheme, IRCs could service the da Vinci and EndoWrists, which would allow for competitive pricing in the da Vinci service and EndoWrist repair and replacement aftermarkets. For example, SIS states that it charges its customers approximately 30-45% less to clean or repair an EndoWrist than Intuitive charges to replace the same EndoWrist. Restore similarly estimates that Intuitive charges at least 25% higher prices on

average for EndoWrist replacement as compared to EndoWrist repairs performed by IRCs. Denying IRCs the ability to service da Vincis causes Plaintiffs and Class members, such as hospitals and clinics, to pay supracompetitive prices for these services. Likewise, denying IRCs the ability to repair EndoWrists causes Plaintiffs and the Class continually to spend thousands of dollars replacing instruments that could be repaired and safely reused throughout those instruments' useful lives.

9. Plaintiffs bring this action on behalf of themselves and a Class of similarly situated direct purchasers to put an end to Intuitive's anticompetitive conduct and remedy the injuries it has caused.

#### **PARTIES**

- 10. Plaintiff Larkin Community Hospital ("Larkin") is a Florida corporation with its principal place of business located in Miami, Florida.
- 11. Larkin leased two da Vincis, an Xi and an Si, from Defendant Intuitive in June 2017, pursuant to written lease agreements. During the proposed Class Period (defined in paragraph 163, infra), Larkin paid for and/or purchased (a) service for its da Vincis, and (b) replacement EndoWrists.
- 12. In 2018, to save significant costs on its EndoWrist service and replacements, Larkin engaged Revanix, an IRC it had used before in connection with the service and repair of other types of medical equipment. Larkin was confident that Revanix could adequately service its EndoWrists at significant cost savings to Larkin. However, before Larkin could hire Revanix, Intuitive threatened to serve Larkin (and Revanix) with cease-and-desist letters and void the warranty on Larkin's da Vincis. Based on those threats, Larkin stopped its efforts to have Revanix service its EndoWrists.

- 13. The agreements associated with Larkins's da Vinci leases required that Larkin use Intuitive as its exclusive servicer for any maintenance of its da Vincis, and that Larkin purchase replacement EndoWrists according to Intuitive's arbitrary use limits. As a result, during the Class Period, for each of its da Vincis, Larkin has regularly paid for and/or purchased from Intuitive (a) maintenance services at supracompetitive prices, and (b) unnecessary replacement EndoWrists. Larkin spent substantially more on da Vinci service and replacement EndoWrists than it would have absent Intuitive's anticompetitive conduct.
- 14. Plaintiff Franciscan Alliance, Inc. operates a not-for-profit healthcare system, known as Franciscan Health, Inc. (collectively, "Franciscan"). Franciscan is one of the largest Catholic healthcare systems in the Midwest, with 13 hospital campuses that serve patients in Indiana, Illinois, and Michigan. During the proposed Class Period, Franciscan paid for and/or purchased (a) service for its da Vincis, and (b) replacement EndoWrists.
- 15. Franciscan has offered minimally invasive robotic surgery to its patients for over a decade, and multiple Franciscan campuses have da Vincis. Once such campus, Franciscan Health Crown Point, in Crown Point, Indiana, first purchased a da Vinci in 2010. Franciscan Health Michigan City, in Michigan City, Indiana, has owned and operated a da Vinci since 2010. And Franciscan Health Dyer, in Dyer, Indiana, has owned and operated a da Vinci since 2012.
- 16. At these and other Franciscan campuses, surgeons regularly use da Vincis to perform minimally invasive robotic surgeries. Surgeons at Franciscan Health Indianapolis, for example, performed 455 da Vinci procedures in 2017 alone. Franciscan surgeons use the da Vinci for a variety of surgeries, including general, gynecologic, colorectal, thoracic, and urologic procedures.
- 17. The agreements associated with Franciscan's purchase of these da Vincis required that Franciscan use Intuitive as its exclusive servicer for any maintenance of its da Vincis, and

that Franciscan purchase replacement EndoWrists according to Intuitive's arbitrary use limits. As a result, during the proposed Class Period, for each of its da Vincis, Franciscan has regularly paid for and/or purchased from Intuitive (a) da Vinci maintenance services at supracompetitive prices, and (b) unnecessary replacement EndoWrists. Franciscan spent substantially more on da Vinci service and replacement EndoWrists than it would have absent Intuitive's anticompetitive conduct.

- 18. Plaintiff King County Public Hospital District No. 1, DBA Valley Medical Center ("Valley Medical"), is a Washington municipal corporation and nonprofit healthcare provider located in Renton, Washington. Valley Medical is the largest nonprofit healthcare provider between Seattle and Tacoma, serving over 600,000 residents. Valley Medical is managed as a component of University of Washington Medicine, subject to the oversight of a Board of Trustees, and includes a hospital and a network of more than 40 primary and specialty care clinics throughout Southeast King County, Washington. During the proposed Class Period, Valley Medical paid for and/or purchased (a) service for its da Vincis, and (b) replacement EndoWrists.
- 19. Valley Medical has used da Vincis, including the Si and Xi, since 2006 at the latest. Today, Valley Medical owns two Xi models, which Valley Medical uses for surgeries and conditions including hysterectomy, fibroid tumor, gynecologic cancer, and other gynecologic surgery. Over the last several years, Valley Medical has averaged nearly 350 surgeries annually using da Vincis. That number has increased in recent years, reaching 430 such surgeries in 2019 alone.
- 20. The agreements associated with Valley Medical's purchase of these da Vincis require that Valley Medical use Intuitive as its exclusive servicer for any maintenance of its da Vincis, and that Valley Medical purchase replacement EndoWrists according to Intuitive's

arbitrary use limits. As a result, during the proposed Class Period, for each of its da Vincis, Valley Medical regularly paid for and/or purchased from Intuitive (a) da Vinci maintenance services at supracompetitive prices, and (b) unnecessary replacement EndoWrists. Valley Medical spent substantially more on da Vinci service and replacement EndoWrists than it would have absent Intuitive's anticompetitive conduct.

- 21. Plaintiff Kaleida Health is a New York not-for-profit corporation with its principal place of business in Buffalo, New York. During the proposed Class Period, Kaleida leased and/or purchased da Vinci Xi models including, without limitation, da Vinci Xi, X, and Si models directly from Defendant Intuitive, pursuant to written agreements, and paid Defendant Intuitive for service to its da Vincis and replacement EndoWrists.
- 22. As a result of Intuitive's antitrust violations, Plaintiffs and members of the Class have been injured in their business or property.
- 23. Defendant Intuitive Surgical, Inc. is a Delaware corporation with its principal place of business at 1020 Kifer Road, Sunnyvale, CA. Intuitive manufactures the da Vinci. Intuitive also manufactures and sells EndoWrists and other accessories used with the da Vinci. Intuitive directly sells da Vincis and EndoWrists, and associated parts and services, to hospitals, clinics, and surgical centers throughout the United States, including in the Northern District of California.

#### **VENUE AND JURISDICTION**

- 24. This complaint is filed under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202, and 15 U.S.C. §§ 15 and 26.
- 25. Defendant transacts business and is found in this district. Substantial interstate trade and commerce involved and affected by the alleged violations of antitrust law occurs

within this district. The acts complained of have had substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22, and 26.

#### **GENERAL ALLEGATIONS**

- A. Relevant Markets and Intuitive's Antitcompetitive Conduct
  - 1. The Minimally Invasive Surgical Robot Market and Intuitive's Monopoly Power in That Market
    - a. The Minimally Invasive Surgical Robot Product Market
- 26. Minimally invasive surgical robots are used for soft tissue surgeries performed between the pelvis and the head. Minimally invasive robotic surgery, like laparoscopic surgery done by hand, makes several small incisions in soft tissue for the insertion of small surgical instruments to perform a surgical procedure. The surgeon, sitting at a computer, uses hand-controls to manipulate the instruments, which are attached to the da Vinci by robotic arms with joints.
- 27. Minimally invasive robotic surgeries largely mirror laparoscopic surgeries that have been performed by hand for decades, but differ in a number of respects, including:
  - i. Stereoscopic high-definition cameras for 3-D visibility;
  - ii. An additional robotic arm, which allows the simultaneous use of three instruments;
  - Wrist joints that allow for an expanded range of motion compared to human mobility;
  - iv. The ability to precisely perform small, discrete movements with the robotic arms and instruments;
  - v. Minimizing surgeon fatigue; and
  - vi. According to Intuitive, decreasing complication rates and reducing the lengths of patient stays.

- 28. There is a relevant product market for minimally invasive surgical robots. Surgical robots have no practical substitute, because although robotic surgery is significantly more expensive and less profitable than traditional laparoscopic surgical procedures, hospitals are expected to offer robotic surgeries.
- 29. In fact, the very characteristics that make minimally invasive surgical robots unique and more expensive – enhanced visualization using high-definition cameras, precise and tremor-free instrument controls, advanced instrumentality, and improved surgeon ergonomics – make minimally invasive robotic surgeries preferable to traditional laparoscopic procedures for many surgeons. Notwithstanding the fact that minimally invasive robotic surgery is itself more expensive than traditional laparoscopic surgery, many hospitals believe that minimally invasive robotic surgery can lower the overall cost to treat per episode by reducing complications, shortening recovery times and hospital stays, and resulting in better long-term health outcomes and higher patient satisfaction than with traditional laparoscopic surgery. Many patients believe minimally invasive robotic surgery will reduce pain and scarring, and regard it as safer and more effective than traditional laparoscopic surgeries. Thus, minimally invasive robotic surgery is in many cases preferable for hospitals and their surgeons and patients.
- 30. The market for minimally invasive surgical robots is a distinct market. For example, although traditional laparoscopic surgeries are far cheaper than robotic alternatives and their outcomes have been reported to be largely equivalent, Intuitive has successfully promoted minimally invasive robotic surgery as a superior alternative to traditional laparoscopic surgery. With patients and doctors demanding robotic options, hospitals are compelled either to offer them or to forego significant business. Intuitive claims that minimally invasive robotic surgeries provide several advantages for surgeons over traditional laparoscopic surgeries, including increased dexterity, improved hand-eye coordination and ergonomic position, and improved

visualization. The robot has more "arms" than a human, which allows the surgeon to hold additional instruments. The "wrists" of the robot have a greater range of motion than a human wrist, which allows for greater dexterity. The movements of the instruments can be scaled relative to the movements of the controller, which allows for greater precision. The console from which the surgeon operates is designed to minimize surgeon fatigue.

- 31. Because of the distinct attributes of surgical robots and Intuitive's aggressive promotion of the da Vinci, many doctors and patients believe minimally invasive robotic surgeries are superior to traditional laparoscopic surgeries. Intuitive advertises that da Vinci surgeries provide patients with "improved outcomes" and "fewer complications" and that a hospital that lacks a da Vinci will provide patients with worse outcomes and more complications.
- Many doctors prefer to perform—and indeed only have the skills to perform— 32. minimally invasive robotic surgeries and not traditional laparoscopic surgeries. They learned how to perform minimally invasive robotic surgeries (in particular, da Vinci surgeries) in medical school, and they have been performing only da Vinci surgeries for years. These doctors will work only at hospitals that have da Vincis.
- 33. Intuitive and many hospitals promote the distinction between da Vinci surgeries and traditional surgeries. They emphasize the alleged superiority of da Vinci surgeries. Intuitive states that "100% of the top-ranked U.S. hospitals for cancer, urology, gynecology and gastroenterology diseases all use da Vinci surgical systems."
- 34. There is very little if any cross-elasticity of demand between surgical robots and laparoscopic surgery equipment, instruments, and service. A 2017 study estimated that the persurgery cost to a hospital of purchasing and maintaining the da Vinci averaged \$1,701, and that hospitals spent an additional \$1,866 per procedure, on average, for the instruments and

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accessories used in a robotic surgery.<sup>3</sup> In traditional laparoscopic surgeries, in contrast, the marginal cost of reusable instruments is less than a few hundred dollars per surgery, and disposable instruments typically cost less than \$1,000.4 Further, most insurance plans pay the same amount for minimally invasive robotic surgery as for the equivalent laparoscopic surgery, such that patients pay much more out of pocket for minimally invasive robotic surgery and hospitals have lower (and sometimes negative) margins on the procedures. Nevertheless, according to Intuitive, the number of robotic surgeries performed increased from 136,000 in 2008<sup>5</sup> to an estimated 1,243,000 in 2020.<sup>6</sup> Intuitive boasts that a surgeon starts a procedure using

choose laparoscopic or traditional surgery instead, nor would a change in the cost of traditional or laparoscopic equipment impact the doctors or patients opting for minimally invasive robotic surgery. Put another way, a hypothetical monopolist of minimally invasive surgical robots could impose a small but significant, non-transitory increase in price without losing meaningful market

a da Vinci surgical robot every 25.4 seconds. Thus, it is apparent that an increase in the cost of a

minimally invasive surgical robot, instruments, and service does not lead doctors or patients to

alternatives without losing sales or revenue streams, but instead steadily increasing its sales over

Intuitive has done just that in the real world, charging substantial premiums over laparoscopic

share to alternative products or services, such as those involved in laparoscopic surgery. Indeed,

time.

<sup>&</sup>lt;sup>3</sup> Christopher P. Childers and Melinda Maggard-Gibbons, Research Letter: Estimation of the Acquisition and Operating Costs for Robotic Surgery, 320 Journal of American Medical Association 835, 836 (August 28, 2018).

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> Intuitive (Form 10-K), at 4 (Feb. 6, 2009).

<sup>&</sup>lt;sup>6</sup> Intuitive (Form 8-K), at 1 (Jan. 13, 2021).

- 35. Likewise, instead of shifting to cheaper laparoscopic equipment for surgeries, hospitals are investing millions in minimally invasive surgical robots, even at much higher prices. Accordingly, neither laparoscopic instruments nor any other devices are substitutable with minimally invasive surgical robots, as hospitals will not switch to those instruments or devices even if the price of minimally invasive robots is raised above competitive levels (as it is for the da Vinci, as well as related service and EndoWrists).
- 36. Minimally invasive surgical robots and traditional laparoscopic surgical equipment occupy separate economic markets. The financial and healthcare press refer specifically to the market for surgical robots and competition in surgical robots. Surgeons can specialize in robotic surgery, and there are several professional and trade associations focused on robotic surgery such as the Society for Robotic Surgery and the Clinical Robotic Surgery Association. Moreover, most manufacturers that make surgical robots specialize in surgical robots. They do not also make equipment for traditional laparoscopic surgeries.
- 37. Founded in 1995, Intuitive designs and manufactures the da Vinci, and markets it directly to its customers in the U.S. The Food and Drug Administration ("FDA") approved the da Vinci for general laparoscopic surgery in 2000.7 It is approved for both adult and pediatric use.
- 38. The da Vinci, pictured below in Figure 1, consists of three main components: the surgeon's console, where the surgeon sits to perform the operation; the patient-side cart, which holds the camera and surgical instruments controlled by the surgeon; and the vision system, which includes a view screen that allows the care team to view the surgery in real time.<sup>8</sup>

<sup>&</sup>lt;sup>7</sup> Intuitive (Form 10-K), at 5 (Feb. 10, 2021).

<sup>&</sup>lt;sup>8</sup> *Id*. at 6.



Figure 1: The da Vinci with attached EndoWrists

- 39. There are four generations of Intuitive da Vincis: the latest generation includes the Xi, X, and SP models. The third generation is the Si model; the second is the S model; and the first-generation is the "standard" model. The da Vinci SP is the latest model to be launched, in 2018. As discussed below, the da Vinci X and Xi models use different EndoWrists than earlier models.
- 40. Intuitive sells the da Vinci directly to hospitals and surgical centers, and also enters lease arrangements directly with certain qualified customers, a practice it started in 2013.<sup>10</sup>

<sup>&</sup>lt;sup>9</sup> *Id.* at 63.

<sup>&</sup>lt;sup>10</sup> *Id.* at 56.

It also has entered use-based arrangements with larger customers. Under such arrangements, hospitals are charged for the robot and service as they are utilized.

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- 41. As of December 31, 2020, Intuitive had an installed base of 3,720 da Vincis in the U.S. <sup>11</sup> The U.S. installed base has increased over 45% in the past four years alone: as of December 31, 2016, Intuitive had an installed base of 2,563 da Vincis in the U.S. <sup>12</sup> Moreover, despite the coronavirus pandemic, the U.S. installed base grew more than 5% in 2020. <sup>13</sup> Intuitive maintains a market share of at least 98% of the minimally invasive surgical robot market and holds similarly high shares in the aftermarkets for da Vinci service and the repair and replacement of EndoWrists.
- 42. The da Vinci is a minimally invasive soft tissue surgical robot and may be used to perform a variety of surgical procedures including general, gynecologic, urologic, cardiothoracic, and head and neck surgeries. While other companies have introduced products in the field of robot-assisted surgery, most of those machines cannot be used for minimally invasive soft tissue surgeries and none is a significant competitor in the minimally invasive surgical robot market. For example, a natural orifice surgical robot allows a surgeon to insert a flexible scope with a camera into the abdominal cavity via one of the body's natural orifices. The surgeon may then perform throat, neck, or colorectal surgical procedures. However, the robot can only operate instruments introduced through the tube inserted into the natural orifice. It also is not indicated for pediatric use. The constraints imposed by both the mode of access and the limited availability of tools for use with natural orifice surgical robots pose several challenges for surgeons and

<sup>&</sup>lt;sup>11</sup> *Id.* at 10.

<sup>&</sup>lt;sup>12</sup> Intuitive (Form 10-K), at 9 (Feb. 6, 2017).

<sup>&</sup>lt;sup>13</sup> Intuitive (Form 10-K), at 10 (Feb. 7, 2020) (3,531 robots in the U.S. as of December 31, 2019).

preclude it from competing in the minimally invasive surgical robot market. Likewise, orthopedic robots, which are designed for assisting in the removal of bone and aligning prosthetics for knee and hip replacement, are not indicated for use in minimally invasive soft tissue surgery and are not a practical substitute for minimally invasive surgical robots.

- 43. In 2020, approximately 876,000 procedures were performed using the da Vinci in the U.S.<sup>14</sup>
- 44. The da Vinci ranges in price from \$500,000 to \$2.5 million. Intuitive reported \$830.7 million in revenue from da Vinci sales in the U.S. in 2019, accounting for 61.7% of robot sales worldwide. 15

#### b. The Geographic Market for Minimally Invasive Surgical Robots

- 45. There is a national geographic market for minimally invasive surgical robots in the U.S. The FDA regulates the approval of all medical equipment in the U.S., including minimally invasive surgical robots. Manufacturers who wish to sell minimally invasive surgical robots in the U.S. must obtain FDA approval before doing so.
- 46. U.S. hospitals cannot lawfully operate non-FDA-approved minimally invasive surgical robots. Thus, minimally invasive surgical robots approved only for use abroad are not substitutes for FDA-approved minimally invasive surgical robots, even though Intuitive has set its da Vinci prices above competitive levels.

#### Intuitive's Monopoly in the U.S. Market for Minimally Invasive Surgical c. **Robots**

47. From 1999 to 2017, the da Vinci robot was the only minimally invasive surgical robot cleared by the FDA for sale in the domestic market. Intuitive installed more than 2,000 da

<sup>&</sup>lt;sup>14</sup> Intuitive (Form 10-K), at 60 (Feb. 10, 2021).

<sup>&</sup>lt;sup>15</sup> Intuitive (Form 10-K), at 87 (Feb. 7, 2020).

Vinci robots during its time as the only manufacturer in the minimally invasive surgical robot market. From 2017 through today, Intuitive has maintained at least a 98% market share in the worldwide and domestic minimally invasive surgical robot markets.

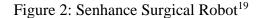
- 48. The number of procedures performed using the da Vinci has typically increased at least 14% year-over-year since 2017, with a 1% decrease in procedures performed in 2020 due to the ongoing Coronavirus pandemic.<sup>16</sup>
- 49. A company called Asensus (formerly known as TransEnterix) received FDA approval for commercial sale of its surgical robot, shown below in Figure 2, in the U.S. in 2017.<sup>17</sup> Sold under the Senhance brand name, the robot is approved to perform gynecological, colorectal, and cholecystectomy surgeries, and inguinal hernia repair. It cannot perform certain surgeries, such as cardiothoracic or urological surgeries, making it less functional than the da Vinci. Nor is it approved for pediatric use. Asensus reported just \$90,000 in revenues from sales related to its Senhance surgical robot in 2019 in the U.S. and has had "limited commercial success to date" in the U.S. <sup>18</sup>

16

<sup>&</sup>lt;sup>16</sup> Intuitive (Form 10-K), at 60 (Feb. 10, 2021).

<sup>&</sup>lt;sup>17</sup> Asensus (f.k.a. TransEnterix) (Form 10-K), at 4 (March 16, 2020).

<sup>&</sup>lt;sup>18</sup> *Id.* at 13.





- 50. Neither Asensus nor any other company is a significant competitor in the minimally invasive surgical robot market.
- 51. While other companies have introduced products in the field of robotic-assisted surgery, these machines are not part of the minimally invasive surgical robot market and thus are not competitors of Intuitive's da Vinci. For example, a company called Medrobotics received clearance for a natural orifice surgical robot on July 23, 2015. However, the robot, sold under the Flex system brand name, can only operate instruments introduced through the tube inserted into the natural body orifice. Thus, due to its design limitations, it is indicated for only a limited range of procedures and is not a direct competitor to the da Vinci. The Flex system has a *de minimis* presence in the marketplace.

17

<sup>&</sup>lt;sup>19</sup> TransEnterix, Inc. Unveils New Brand Identity for Robotic Surgical System: Establishes Senhance™ to Communicate New Era in Robotic Surgery, BusinessWire (Sept. 7, 2016), https://www.businesswire.com/news/home/20160907005187/en/TransEnterix-Inc.-Unveils-New-Brand-Identity-for-Robotic-Surgical-System.

- 52. Medtronic and Stryker make devices for use in orthopedic surgeries. Medtronic makes the Mazor X Stealth device for use specifically in spinal implant surgery, and Stryker makes the Mako products for use in aligning implants in knee and hip replacement surgeries. These orthopedic surgery robots are not substitutes for, and do not compete with, Intuitive's da Vinci robots, which are not used for orthopedic surgeries. The orthopedic surgery robots are not part of the minimally invasive surgical robot market.
- 53. Prior to FDA approval of the Senhance for minimally invasive robotic surgeries, Intuitive maintained a 100% market share for minimally invasive surgical robots. Even after Senhance and Medrobotics entered the robotic surgery market, Intuitive still maintains at least a 98% market share in the market for minimally invasive surgical robots because neither company has been able to gain sufficient U.S. market share to pose a meaningful threat to Intuitive's dominance. While Intuitive shipped 728 da Vincis throughout the U.S. in 2019, Asensus did not ship any Senhances domestically and Medrobotics shipped fewer than 10 Flex robots worldwide.
- 54. External literature characterizes Intuitive as possessing monopoly power in the minimally invasive surgical robot market. For example, one 2017 study in the Journal of Minimal Access Surgery noted that Intuitive's da Vinci was "the only commercially available robotic equipment" at the time. Similarly, a 2019 study on robotic surgery noted that Intuitive "[e]ffectively [possessed] a monopoly" in the robotic surgery industry.

<sup>&</sup>lt;sup>20</sup> Gkegkes, I. D., Mamais, I. A., & Iavazzo, C. (2017). Robotics in General Surgery: A Systematic Cost

Assessment. Journal of Minimal Access Surgery, 13(4), 243–255. Https://Doi.Org/10.4103/0972-9941.195565

<sup>&</sup>lt;sup>21</sup> Perez, R. E. & Schwaitzberg, S. D., Robotic Surgery: Finding Value in 2019 and Beyond, Ann. Laparosc. Endosc. Surg. 2019; 4:51.

55. Switching minimally invasive surgical robots is not feasible. First, minimally invasive surgical robots require significant capital investment not only in the robot itself but also in the necessary surgical instruments and required service contracts. Further, operating a minimally invasive surgical robot requires many hours of training. Switching minimally invasive surgical robots would not only be costly—as minimally invasive surgical robots have an average sales price of \$1.5 million and many of Intuitive's U.S. customers have at least two such robots, representing significant capital investment—but also would require substantial time to retrain surgeons and supporting staff to operate the new robot, during which time a hospital may not be able to offer minimally invasive robotic surgical services. Surgeons at a hospital attempting such a transition would need to abandon the da Vinci surgical methods they have been performing for years (for some, their entire careers) and learn how to perform surgeries with different minimally invasive surgical robots. This process would be both costly and likely to generate substantial resistance, particularly given that Intuitive invests heavily to ensure that doctors and medical students are trained to use, and be dependent on, the da Vinci. Intuitive has aggressively marketed da Vincis and has paid surgeons substantial sums—in some cases, millions of dollars to promote da Vincis by, e.g., giving talks about them, teaching others how to use them, and testing and writing reviews of them. Some surgeons would switch hospitals rather than switch minimally invasive surgical robots, further driving up costs for any hospital that sought to replace the da Vinci with competing robots. Finally, according to Restore, Intuitive extracts from its da Vinci customers the contractual commitment not to purchase competing robots.<sup>22</sup>

<sup>&</sup>lt;sup>22</sup> Restore Second Amended Complaint (March 29, 2021) (ECF No. 77) ("Restore Second Amended Complaint") ¶ 23, Restore Robotics, LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55-TKW-MJF (N.D. Fl.).

- 56. There are high barriers to entry into the minimally invasive surgical robot market. The cost to develop a minimally invasive surgical robot is substantial, especially because Intuitive maintains an extensive portfolio of patents that block the development of competing minimally invasive surgical robots. Indeed, Intuitive has stated in a court pleading that as of December 31, 2018, it held ownership or exclusive field-of-use licenses for more than 3,000 U.S. and foreign patents. Intuitive is notorious for aggressively amassing and enforcing these patents. Furthermore, clearance by regulatory agencies, such as the FDA, is an extensive and
  - 2. The da Vinci Service Aftermarket and Intuitive's Stifling of Competition in That Aftermarket
    - a. The da Vinci Service Aftermarket

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uncertain process.

- 57. The medical equipment repair and maintenance services industry is a \$3.3 billion market in the U.S. and is expected to grow by 1.5% per year between 2020 and 2025.<sup>24</sup>
- 58. There is a relevant aftermarket in the U.S. for the service of da Vincis. After the da Vinci is installed, it requires regular maintenance and service. The primary aspects of the da Vinci service aftermarket are the routine maintenance of the da Vinci and the repair of the da Vinci when necessary.
- 59. Recognizing this need for regular repair and maintenance, Intuitive conditions the purchase or lease of a da Vinci on the customer entering into a da Vinci service contract.<sup>25</sup> The initial service contract is typically five years, with the first year of service being free and the

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<sup>&</sup>lt;sup>23</sup> Intuitive's Answer and Affirmative Defense (Sept. 30, 2019) (ECF No. 32) ¶ 23, *Restore Robotics, LLC v. Intuitive Surgical, Inc.*, Case No. 5:19-cv-55-TKW-MJF (N.D. Fl.).

<sup>&</sup>lt;sup>24</sup> Jack Curran, "Medical Equipment Repair & Maintenance Services," IBIS World, June 2020, at 7.

<sup>&</sup>lt;sup>25</sup> Intuitive (Form 10-Q), at 29 (June 2020).

remaining four years ranging in price from \$80,000 to \$190,000 per year. <sup>26</sup> At present, Intuitive requires its customers to purchase one of two types of service plans for its da Vincis, either:

- i. the Complete Care Service Plan, which includes advance exchange program, remote software update, sterile reprocessing support, technical support, onsite access and monitoring, and da Vinci surgery customer portal; or
- ii. the Premium Care Service Plan, which includes everything in the Complete Care service plan and provides extended service hours, faster response time, expedited replacement parts, and a 5% discount on technology upgrades, among other things.<sup>27</sup>
- 60. At the end of each contract term, Intuitive offers an additional service contract. Intuitive uses its exclusive access to certain replacement robot parts, as described below, see *infra* at paragraphs 65-66, to pressure its customers to renew their service contracts.
- 61. The terms of the service contracts exempt Intuitive from its obligation to perform any service or repair if the customer or a third party (such as an IRC) services the da Vinci, even if Intuitive's service contract did not cover the service.
- 62. Customers have little or no information for projecting the costs of surgical robot parts or service, even with flat-rate service agreements. In order to forecast the cost per use, the customer must know how often the robot will be used. However, customers typically cannot forecast demand for a surgical robot: surgeons may have varying degrees of adaptation to a surgical robot at a new location or for a new procedure; competing hospitals may or may not acquire their own robots; and the FDA may or may not add new indications for use of the robots.

<sup>&</sup>lt;sup>26</sup> Intuitive (Form 10-K), at 55 (Feb. 10, 2021).

<sup>&</sup>lt;sup>27</sup> Da Vinci service plan brochures are available at https://www.intuitive.com/en-us/productsand-services/da-vinci/services##.

These and other unknown factors will impact how often a da Vinci is used, and thus bear on part replacement and service costs.

- 63. There are high barriers to entry in the da Vinci service aftermarket. First, the terms of the da Vinci Sales Agreements and the tied da Vinci service contracts prohibit customers from servicing their da Vinci either themselves or through an IRC. Lessees of the da Vinci must enter the same service contract for the term of the lease. This discourages customers from seeking da Vinci repair or maintenance services from IRCs.
- 64. Intuitive encrypts and hides from robot owners and IRCs the service software necessary to: (a) test the robot arms during preventative maintenance; (b) input Intuitive serial numbers after replacing da Vinci robot parts; and (c) remove the reminder message after performing preventative maintenance or repairing the robot.
- 65. Intuitive is also the only manufacturer of da Vinci robot parts. For calendar year 2020, Intuitive had an overall gross margin on product sales of more than 66%, a slight dip from the pre-pandemic gross margin of more than 70% on product sales that Intuitive enjoyed in calendar year 2019. Upon information and belief, Intuitive realizes gross margins in excess of 90% for da Vinci parts.
- 66. Da Vinci parts are not available from other sources. This is due in part to patent protection and development costs, but also to the fact that, in at least some instances, the da Vinci requires an Intuitive product serial number for the replacement part in order to restart the robot. Intuitive also excludes competition in the sale of da Vinci parts by requiring customers to purchase a parts and service plan from Intuitive with the purchase or lease of the da Vinci. Intuitive requires customers to purchase da Vinci service from Intuitive to get access to da Vinci parts, and sells da Vinci parts only directly to da Vinci customers and only as part of the robot service.

- 67. Quality control is not a valid business justification for excluding third parties from servicing and repairing da Vincis. Indeed, Intuitive contracts with third party distributors of da Vincis outside the U.S. to service da Vincis.
- 68. While servicing the da Vinci requires specialized training and knowledge, there are IRCs that have the skill and capacity to service da Vincis. For example, Restore, a surgical robotic repair company based in Florida, specializes in the da Vinci and hires da Vinci—certified field service engineers with prior training and experience working at Intuitive to provide da Vinci service. Restore began offering service contracts for the da Vinci in 2018 and typically offers service at rates of less than 50% of the effective rates offered by Intuitive. Restore states that it can service da Vincis worldwide. Great Lakes Robotics ("Great Lakes") is another IRC that claims to be an "authorized" provider of da Vinci services through its partnership with Restore.<sup>28</sup> Other biomedical service and repair companies likely would enter the market to service da Vincis in the absence of Intuitive's anticompetitive conduct.

### b. The da Vinci Service Geographic Aftermarket

- 69. Intuitive installs and services da Vincis throughout the U.S., and U.S.-based IRCs such as Restore have the expertise to service da Vincis throughout the U.S.
- 70. Intuitive sells and services da Vincis through third party distributors in unspecified countries outside the U.S. and provides them with a toolkit with all the documentation, software, and passwords necessary to service the da Vinci. Distributors may use their toolkits to service da Vincis only in their territory. No one else has access to the toolkit, not even customers.

<sup>&</sup>lt;sup>28</sup> https://www.greatlakesrobotics.net/

- 71. U.S. hospitals are thus unable to hire service providers from other countries, despite Intuitive raising its da Vinci service prices above competitive levels.
  - c. Intuitive's Stifling of Competition in the da Vinci Service Aftermarket
- 72. Intuitive exploits its monopoly power in the primary market for minimally invasive surgical robots to acquire and maintain monopoly power in the aftermarket for da Vinci service. Thus, it can and does exclude competition and maintain supracompetitive prices for da Vinci service.
- 73. First, as described above, Intuitive uses contractual ties to lock its da Vinci customers into servicing agreements with Intuitive, rather than any IRCs. The terms of the Sales Agreements and service agreements forbid purchasers from using third party repair or maintenance services of any kind. Intuitive even reserves the right to void the entire service contract of any customer that seeks any kind of service, maintenance, or repair for its da Vinci through an IRC. This effectively forecloses competition in the da Vinci service aftermarket.
- 74. *Second*, as also described above, Intuitive designed the da Vinci to minimize the ability of a third-party to perform maintenance on or manufacture replacement parts for the robot.
- 75. *Third*, as described below, Intuitive aggressively enforces these contractual and technological ties in order to prevent any IRC from developing substantial market share or reaching efficient scale in the aftermarket for da Vinci service.
- 76. All these measures deter customers from attempting to service their da Vincis through an IRC, further solidifying Intuitive's monopoly in the da Vinci service aftermarket.
- 77. For example, when Intuitive learned that a hospital system was using Restore for robot service, Intuitive informed the customer that its hospitals would not be able to purchase da Vinci parts for use in any service performed by Restore. On or about February 12, 2019, Intuitive

also sent a letter to Restore demanding that Restore "immediately cease and desist" from "contacting Intuitive's customers to offer services related to Intuitive's products."

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78. Intuitive's exclusionary conduct in the aftermarket for da Vinci service is further illustrated by its response when Ardent Health Service ("Ardent") used Restore to service da Vincis. Ardent, owner of Hillcrest Medical Center and Hillcrest Hospital South ("Hillcrest") in Tulsa, Oklahoma, allowed its da Vinci service contracts with Intuitive to expire for its two robots at Hillcrest Medical Center and its one robot at Hillcrest Hospital South. Ardent had not been having any problems with the robots. Intuitive was aware that Hillcrest was considering Restore for its da Vinci service.<sup>29</sup>

79. On December 27, 2019, Intuitive removed Hillcrest from the customer portal and placed the three robots on time-and-materials status for any robot service, which includes a travel and labor rate of \$995 per hour. On that same day, Hillcrest Medical Center noticed a blank vision cart touchscreen on one of its robots. Intuitive informed Hillcrest that the monitor needed to be replaced and quoted time and materials of more than \$25,000. Hillcrest hired Restore to troubleshoot the issue. On January 11, 2020, Restore installed a new power supply for the touchscreen monitor and confirmed that the robot was fully functioning. The price was \$7,100.<sup>30</sup>

80. On January 14, 2020, Hillcrest reported an issue with a robot arm on the da Vinci at Hillcrest Hospital South. Intuitive informed Hillcrest that it would cost more than \$100,000 to replace the arm plus an additional sum for preventative maintenance for the da Vinci to be operational. Hillcrest contacted Restore to troubleshoot the issue. Restore informed Hillcrest that Restore could replace the arm if necessary but did not have the toolkit to access the robot

<sup>&</sup>lt;sup>29</sup> Restore Second Amended Complaint ¶ 64.

 $<sup>^{30}</sup>$  *Id.* at ¶ 65.

software and input the serial number for the replacement arm. Intuitive would have to input the serial number for any replacement arm for the da Vinci to be operational.<sup>31</sup>

- 81. On January 16, 2020, Restore was able to repair, rather than replace, the robot arm for \$3,975. The da Vinci was operational but had two remaining error codes. Restore could not troubleshoot the remaining errors without access to the software on the da Vinci and informed Hillcrest that it would need to contact Intuitive regarding the remaining error codes.<sup>32</sup>
- 82. On January 17, 2020, Kara Andersen Reiter, Intuitive SVP and General Counsel, and Romain St. Denis, Intuitive VP, notified the CEO, the VP of Risk Management, and the Chief Medical Officer of Ardent Health Services in writing that Intuitive had learned that Ardent was "having or intends to have" its da Vincis serviced by an "unauthorized third party." 33
- 83. In the letter, Intuitive explained that third parties did not have the "software tools necessary for proper System maintenance." Intuitive further stated that "Intuitive may no longer accept your service calls for Systems that were previously serviced by an unauthorized third party. Should Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been previously serviced by an unauthorized third party, Intuitive may not provide service for such a System."<sup>34</sup>
- 84. On January 30, 2019, Chris Goss, the Intuitive field service engineer responsible for Hillcrest, contacted the surgery manager at Hillcrest Medical Center in Tulsa, Oklahoma.

  Mr. Goss explained he could monitor the da Vinci remotely and threatened to shut down the da

 $<sup>^{31}</sup>$  *Id.* at ¶ 66.

 $<sup>^{32}</sup>$  *Id.* at ¶ 67.

 $<sup>^{33}</sup>$  *Id.* at ¶ 68.

 $<sup>^{34}</sup>$  *Id.* at ¶ 69.

Vincis at Hillcrest if the hospital signed a service contract with Restore. Mr. Goss said Intuitive would make Hillcrest's da Vincis "a big paper weight" if Hillcrest chose to use a third party for its robot service.<sup>35</sup>

- 85. Shortly thereafter, the da Vinci ceased to function in the middle of a procedure. The surgeon had to convert the procedure to open surgery with the patient on the operating table. Afterwards, Hillcrest disconnected the data cable that provides the remote connection between the da Vinci and Intuitive.<sup>36</sup>
- 86. On May 6, 2020, Hillcrest contacted Restore to troubleshoot a robot arm on the da Vinci in one of its operating rooms at Hillcrest Medical Center. Restore reminded Hillcrest that Intuitive would have to perform any repair of the robot arm because the repair or replacement of the arm would require access to the da Vinci software through the service laptop and the service keys and that Intuitive does not provide such access to the owner or IRCs.<sup>37</sup>
- 87. On May 7, 2020, Hillcrest contacted Intuitive for repair of the robot arm on a time-and-materials basis. Intuitive quoted an initial price to troubleshoot the arm. Ardent approved the quote. Later that day, Intuitive revised its quote to include an additional sum for preventative maintenance. Early on May 8, 2020, Ardent approved the work order.<sup>38</sup>
- 88. Later that day, Intuitive instructed its field service engineer to cease the repair of the robot arm because the engineer observed that other parts elsewhere on the da Vinci had not been installed by Intuitive. On May 11, 2020, Intuitive demanded that Ardent agree to the removal of any parts that had been replaced or repaired by anyone other than Intuitive and pay

 $<sup>^{35}</sup>$  *Id.* at ¶ 70.

 $<sup>^{36}</sup>$  *Id.* at ¶ 71.

 $<sup>^{37}</sup>$  *Id.* at ¶ 72.

 $<sup>^{38}</sup>$  *Id.* at ¶ 73.

the additional sum to Intuitive for "preventative maintenance" on the da Vinci, in addition to the cost of the repair of the robot arm, before Intuitive would restore functionality to the da Vinci. In fact, the sole "part" that Restore had replaced was the battery, which Restore had replaced with the exact same model from the exact same battery manufacturer.<sup>39</sup>

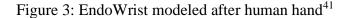
- 89. On May 12, 2020, Ardent agreed to the demands and beseeched Intuitive to "fix the robot ASAP." Shortly thereafter, Ardent signed a one-year service contract with Intuitive for the da Vinci in question at Hillcrest retroactive to the prior contract expiration date of December 27, 2019 at a price of more than \$100,000.<sup>40</sup>
- 90. As a direct result of this type of exclusionary conduct, Intuitive has maintained a market share in the da Vinci service aftermarket of more than 99% for nearly 20 years. In 2019, Intuitive reported \$508.4 million in revenues for service to its customers in the U.S.
  - 3. The EndoWrist Repair and Replacement Aftermarket and Intuitive's **Suppression of Competition in that Aftermarket** 
    - a. The EndoWrist Repair and Replacement Aftermarket
- 91. There is a relevant aftermarket for the repair and replacement of EndoWrists that is separate from the minimally invasive surgical robot market and the da Vinci service aftermarket (the "EndoWrist Repair and Replacement Aftermarket"). EndoWrists are the only FDA-approved surgical instruments that are compatible with the da Vinci. Therefore, hospitals must have EndoWrists in order to use the da Vinci.
- 92. Intuitive exercises complete control over the design, manufacture, sale, and replacement of EndoWrists. Although Intuitive maintains a significant patent portfolio in its surgical robots, any blocking patents for its EndoWrist instruments are long expired. Intuitive

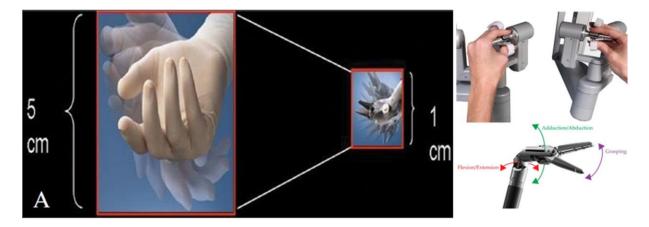
 $<sup>^{39}</sup>$  *Id.* at ¶ 74.

 $<sup>^{40}</sup>$  *Id.* at ¶ 75.

maintains a "Patent Notice" web page for its products. Virtually all the patents covering core structure and operations for the "EndoWrist" and "Accessories" are expired.

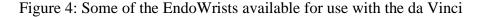
93. Intuitive sells over 80 different types of surgical instruments for use with the da Vinci. As shown in Figure 3, below, EndoWrists are modeled after the human wrist and offer a greater range of motion than the human hand. Figure 4, below, depicts some of the EndoWrists available to hospitals.

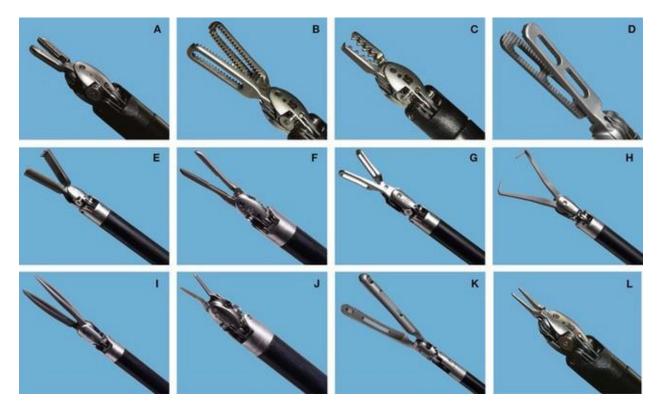




<sup>&</sup>lt;sup>41</sup> Palep J. H. (2009). Robotic assisted minimally invasive surgery. Journal of minimal access surgery, 5(1), 1–7. https://doi.org/10.4103/0972-9941.51313; Intuitive; and Longmore, S. K., Naik, G., & Gargiulo, G. D. (2020).

Laparoscopic Robotic Surgery: Current Perspective and Future Directions. Robotics, 9(2), 42.





- 94. Intuitive sells a variety of EndoWrists with different tips for various surgical actions, including forceps, scissors, scalpels, and clamps. The movement at the instrument tip is controlled by tungsten cables located within the EndoWrist. (Tungsten cables are common in surgical robots, and surgical cables are among the parts that IRCs commonly repair.) These tungsten cables are actuated by internal pulleys of the EndoWrist that mechanically interface with motors within the robot arms of the da Vinci. The motors within the robot arms in turn cause the movement of the instrument tip commanded by the surgeon by pulling or relaxing the tungsten cables. For the vast majority of EndoWrists, these mechanical components provide for all controls of the EndoWrist's instrument tip.
- 95. The da Vinci was designed to work exclusively with instruments manufactured and sold by Intuitive. Thus, EndoWrists are the only instruments compatible with the da Vinci.

- 96. Intuitive installs a programmable memory chip inside each EndoWrist that limits the number of times the instrument may be used. The chip does not control the movement of the EndoWrist instrument tip, but instead stores certain information about the particular EndoWrist, including a model number specific to the type of EndoWrist, a part ID specific to the particular EndoWrist, a chip ID for the chip itself, and a counter value for the particular EndoWrist.
- 97. The counter counts the number of times the EndoWrist is attached to a da Vinci robot arm, not an actual measure of use such as usage time, number of movements, or actuation time. The chip also does not monitor the components of the EndoWrist for conditions that could be indicative of actual or impending failure, such as the lack of response of the instrument tip to requested movement or a motor requiring excessive force to cause a desired movement of the tungsten cables.
- 98. The da Vinci queries the memory chip prior to performing any operations with the particular EndoWrist. After a certain number of uses the chip wipes itself and, because the da Vinci cannot identify the EndoWrist after the memory-wipe, the EndoWrist is rendered nonoperational, based solely on the number of times it is attached to a da Vinci robot arm, without regard to the actual physical condition of the EndoWrist. A majority of EndoWrists have a maximum use limit of ten.
- 99. EndoWrists are a separate product from da Vincis themselves. Although the two are complementary products, there is demand for repair and replacement of EndoWrists separate from demand for da Vincis, and Intuitive sells replacement EndoWrists separately from da Vincis, in part because EndoWrists may wear out over time and need repair or replacement. Just as a car owner whose new tires wear down would not purchase a new car for its tires, but instead would either buy new tires or get her current tires retreaded, da Vinci owners do not purchase a new da Vinci with EndoWrists whenever their EndoWrists cease to be operative. Instead, they

simply purchase replacement EndoWrists from Intuitive (since Intuitive effectively prevents

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repair of EndoWrists).

- 100. Intuitive's quotes for da Vinci robots typically do not include operating EndoWrists (they do sometimes include a small set of training instruments); EndoWrists are quoted using separate prices on a separate quote sheet. Moreover, da Vinci Sales Agreements specify that EndoWrists are to be purchased separately pursuant to the terms and conditions of instrument catalogs. To facilitate the sale of replacement EndoWrists, Intuitive has an EndoWrist sales division with its own personnel separate and apart from the sales division and personal responsible for da Vincis.
- 101. Further demonstrating that the EndoWrist Repair and Replacement Aftermarket is a distinct product market from the market for da Vincis, there is independent demand for EndoWrist repair (as discussed in more detail below), which is provided as a standalone service by IRCs such as Restore, Rebotix, Revanix, and SIS.
- 102. Intuitive itself explicitly distinguishes between da Vincis and EndoWrists as separate products with separate revenue streams. A 2015 investor presentation created by Intuitive, for example, identified Intuitive's "[e]xtensive instrument and accessory product line" as a distinct "Corporate Asset." (Intuitive consistently describes EndoWrists as comprising the majority of its "instrument" offerings, including in SEC filings and EndoWrist/instrument catalogs.) The presentation also described Intuitive's plans to introduce "additional products," which other parts of the presentation make clear included new EndoWrists, for the already available Xi. Intuitive has in fact repeatedly launched new EndoWrist products subsequent to the launch of the particular da Vinci model with which they are compatible, further highlighting

<sup>&</sup>lt;sup>42</sup> Intuitive Investor Presentation Q3 2015, at 38.

<sup>&</sup>lt;sup>43</sup> *Id.* at 37.

how these are separate products. Moreover, Intuitive has sought and received FDA clearances for its EndoWrists separately from the clearance it has received for the da Vinci.

103. Intuitive's SEC filings also show that Intuitive recognizes EndoWrists and da Vincis as separate products. Under a header describing "Intuitive Surgical's Products and Services," for example, Intuitive's 10-K filed in March 2006 stated: "Our principal products include the da Vinci Surgical System and a variety of multiple-use EndoWrist instruments and accessories."44 The same section goes on to describe the "da Vinci Surgical System" and its "components" separately from EndoWrists. 45 Intuitive also consistently distinguishes between its "recurring" revenue streams from EndoWrist sales and its one-time revenues from sales of da Vinci robots. For example, in its 10-K from March 2006, Intuitive stated, "After the initial sale of the da Vinci Surgical System into customer accounts, we generate recurring revenue as our customers use the da Vinci Surgical System to perform surgery and, in the process, buy and consume our EndoWrist instruments and accessory products."46 The same document noted how Intuitive "launched several new instrument products during 2005, including the energy-based, monopolar shears and the harmonic shears . . . . "47 In contrast, Intuitive described its software as "incidental" to the da Vinci as a whole and "not sold or marketed separately." 48

104. The EndoWrist Repair and Replacement Aftermarket is significantly larger than either the primary da Vinci market or the da Vinci service aftermarket. Intuitive's revenues from the sale of instruments and accessories in the U.S. totaled \$1.79 billion in 2019, and despite the

<sup>&</sup>lt;sup>44</sup> Intuitive (Form 10-K), at 6 (Mar. 15, 2006).

<sup>&</sup>lt;sup>45</sup> *Id.* at 6-7.

<sup>&</sup>lt;sup>46</sup> *Id.* at 33.

<sup>&</sup>lt;sup>47</sup> *Id.* at 34.

<sup>&</sup>lt;sup>48</sup> *Id.* at 55.

Coronavirus pandemic, 2020 instrument and accessory revenues were an estimated \$1.785 billion.<sup>49</sup> By comparison, Intuitive reported revenues of \$830 million from robot sales and \$508 million from service contracts in 2019.<sup>50</sup>

105. Indeed, the vast majority of Intuitive's EndoWrist revenue and profit, and thus its overall revenue and profit, comes from the *replacement* of EndoWrists. This is because while a da Vinci represents a large initial investment for Intuitive's customers, they are typically in service for five years, if not a decade, while EndoWrists must be replaced, typically after a mere ten uses, thus providing Intuitive with a recurring revenue stream. Indeed, the bulk of Intuitive's revenue and profit growth over the last decade in the U.S. comes from its sale of its simple EndoWrists, not its complex, multi-million-dollar robots, as demonstrated by the revenue figures from Intuitive's 10-Ks from 2001 to 2020 below:<sup>51</sup>

Year	Instruments (\$M)	Robots (\$M)
2001	\$5.0	\$44.2
2002	\$10.1	\$56.3
2003	\$18.8	\$61.8
2004	\$37.5	\$78.8
2005	\$67.8	\$124.6
2006	\$111.7	\$205.9
2007	\$191.6	\$324.4
2008	\$293.0	\$455.3

<sup>&</sup>lt;sup>49</sup> Intuitive (Form 10-K), at 98 (Feb. 10, 2021).

<sup>&</sup>lt;sup>50</sup> Intuitive (Form 10-K), at 87 (Feb. 7, 2020).

<sup>&</sup>lt;sup>51</sup> These charts reflect Intuitive's worldwide revenues; revenues by region are unavailable prior to 2017.

Year	Instruments (\$M)	Robots (\$M)
2009	\$389.4	\$490.5
2010	\$528.8	\$660.3
2011	\$701.1	\$777.8
2012	\$903.3	\$932.9
2013	\$1,033	\$834.9
2014	\$1,070	\$632.5
2015	\$1,198	\$721.9
2016	\$1,396	\$800.0
2017	\$1,637	\$928.4
2018	\$1,962	\$1,127
2019	\$2,408	\$1,346
2020	\$2,455	\$1,178

106. Because of Intuitive's exclusionary conduct, the EndoWrist Repair and Replacement Aftermarket is dominated by Intuitive's sales of replacement EndoWrists rather than the servicing (i.e., cleaning, sharpening, or repairing) of EndoWrists that the da Vinci customers already own. The replacement EndoWrists sold by Intuitive and the EndoWrist repair services provided (or that could be provided) by IRCs are substitutable. For instance, hospitals hire Rebotix to inspect and repair EndoWrists by, for example, tightening the graspers or sharpening the scissors. And SIS entered into contracts with several hospitals and health care systems to provide EndoWrist repair services. More hospitals would substitute EndoWrist replacement from Intuitive with these services in the absence of Intuitive's exclusionary scheme.

- 107. Intuitive's Sales Agreements require hospitals to replace their EndoWrists exclusively with new EndoWrists purchased from Intuitive. Per these contracts, Intuitive has the right to void warranties associated with the da Vinci itself if unauthorized or unapproved instruments are used with the da Vinci. This causes hospitals to continually purchase replacement EndoWrists from Intuitive or risk voiding their service agreements for not just the serviced EndoWrist(s) but also the da Vinci itself.
- 108. Intuitive's standard Sales Agreements tie the purchase or lease of a da Vinci to its "maximum number of uses" requirement for EndoWrists. The use requirement applies to every single EndoWrist, regardless of its condition or whether it could be used in additional procedures.
- 109. Before releasing its EndoWrists to market, Intuitive told the FDA that the EndoWrists and traditional instruments "are essentially identical . . . in terms of shape, size, function, and tissue effect"; "are substantially equivalent in intended use and/or method of operation"; and "demonstrate substantial equivalence . . . in terms of safety and effectiveness." The FDA agreed and "determined the [EndoWrist] device" is "substantially equivalent" to the traditional devices. Instruments used in traditional laparoscopic surgeries are cleaned and inspected before and after each surgery and may be repaired between procedures, making them usable for hundreds of surgeries. Likewise, because EndoWrists and traditional instruments are similar in many ways, including as to their surgical ends, EndoWrists could be used for dozens—and in some cases over 100—procedures, if inspected and repaired as needed between surgeries.
- 110. The FDA permits servicing of approved medical devices by third parties, going so far as to conclude that "[t]he continued availability of third party entities to service and repair

medical devices is critical to the functioning of the U.S. healthcare system."52 In such cases, third-party service providers repair instruments to meet their original intended use without affecting the safety and effectiveness of the instrument or its indications for use. The instrument is maintained at, or returned to, its original safety and effectiveness. Indeed, the FTC recently quoted the FDA's conclusion in a 2018 Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices that "the objective evidence indicates that many . . . third party entities provide high quality safe, and effective servicing of medical devices."53

- 111. After undergoing third-party service, EndoWrists have passed third-party simulated life-testing to 50 or more additional uses. This is consistent with the fact that EndoWrists used for training purposes commonly last for well over 100 uses, as described below. However, Intuitive takes active measures to preclude EndoWrists from having this longevity for its customers.
- As shown below in Figure 5, EndoWrists are in many respects nearly 112. indistinguishable from manually operated surgical tools. Both are made from medical grade materials, such as stainless steel and composites, that typically last through hundreds of surgeries.<sup>54</sup> Figure 5 includes an EndoWrist on the left and a traditional, manually manipulated tool on the right, and illustrates that their surgical ends are nearly identical.

<sup>&</sup>lt;sup>52</sup> FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), at i, available at https://www.fda.gov/media/113431/download (last visited on September 10, 2021).

<sup>&</sup>lt;sup>53</sup> Nixing the Fix: An FTC Report to Congress on Repair Restrictions (May 2021), at 51, n.284 (quoting FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018)), available at https://www.ftc.gov/system/files/documents/reports/nixing-fix-ftcreport-congress-repair-restrictions/nixing the fix\_report\_final\_5521\_630pm-508\_002.pdf (last visited on September 10, 2021).

<sup>&</sup>lt;sup>54</sup> Rebotix Complaint ¶ 39.

Figure 5: EndoWrist forceps vs. Traditional manual forceps





- However, despite being "substantially equivalent" to traditional laparoscopic 113. instruments, Intuitive limits most EndoWrists to just ten uses, dramatically fewer than their manually operated counterparts.
- To enforce this arbitrary restriction, Intuitive installs memory chips in its 114. EndoWrists that ostensibly count the number of "uses," though, as discussed above, the chip actually counts the number of times the EndoWrist is simply attached to a da Vinci robot arm, rather than its actual use. Intuitive has exclusive control over the use counter, and once the counter hits its limit, the chip renders the EndoWrist non-functional by wiping its memory so that the EndoWrist can no longer communicate with the da Vinci. Intuitive has designed the EndoWrists to prevent the use counter from being bypassed or reset.
- 115. The maximum use requirement for EndoWrists is not based on safety or effectiveness considerations. First, Intuitive has never provided its customers or the FDA any clinical or scientific data to support its use limits; Intuitive's own instrument catalogs demonstrate that the useful lives of the EndoWrists are much longer than their use limits. Yet irrespective of the actual condition of the EndoWrist once it hits ten uses, it must be replaced without exception. Second, Intuitive described the EndoWrist to the FDA as possessing substantial equivalence in terms of safety and effectiveness to its manually manipulated

counterparts, which have no predetermined use limits. Third, when Intuitive sells EndoWrists for training purposes, the use limits are much higher than the exact same tools sold for surgical use, with no demonstrable or practical difference between the two. Nor does the surgical equipment industry distinguish between an instrument sold for clinical use and the same instrument sold for training use. Training instruments, like instruments for clinical use, must retain their functionality for the surgeon during use. The only difference is the generation of revenue for the hospital on a surgical procedure for an instrument in clinical use. Indeed, whereas Intuitive places an artificial use limit of ten on many EndoWrists, Intuitive employees conducting training sessions have used these same EndoWrists 100 to 150 times without issue. Intuitive has stated that the maximum use requirement allows Intuitive to "sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis," but there are no medical necessity or patient welfare concerns motivating Intuitive's use caps; rather, the use limits reflect Intuitive's desire and ability to charge supracompetitive prices.55

116. Use limits are not based on any FDA regulations. The surgical instruments used with Asensus' Senhance do not have use limits. Traditional laparoscopic instruments do not have use limits.

117. As recently as November 12, 2020, Intuitive submitted a 510(k) premarket notification summary to the FDA for several EndoWrists. The summary does not reference any clinical or scientific data showing that the EndoWrists lose their functionality after reaching the ten-use limit. Nor did Intuitive indicate that EndoWrists could not be serviced or repaired to make them safe and effective after reaching the ten-use limit.

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<sup>&</sup>lt;sup>55</sup> See Intuitive (Form 10-K), at 6 (March 30, 2001).

- 118. Customers cannot predict their costs for EndoWrists. Intuitive has complete control over EndoWrist use limits and can (and has) changed the use limits and instructions for use unilaterally and without notice. For example, Intuitive issued instructions for use ("IFU") for EndoWrists, setting a maximum number of autoclave cycles, which sterilize the EndoWrists using steam pressure. Because of the way that da Vinci surgeries are prepped and performed, EndoWrists must often undergo an autoclave cycle even if not actually attached to a robot during surgery. The specified limit on autoclave cycles is extremely low compared to comparable devices made of similar medical grade materials. These unilateral changes can require early replacement, even if the counter has not hit its maximum use limit. They also substantially increase (a) the per-surgery cost of EndoWrists to hospitals, and (b) Intuitive's supracompetitive EndoWrist profits, without prior notice to hospitals. Intuitive, as the sole manufacturer of EndoWrists, exercises complete control over EndoWrist replacement prices. Thus, customers cannot reasonably predict the timing or pricing for replacing EndoWrists.
- 119. Intuitive has imposed arbitrary technological barriers that prevent IRCs and others (such as manufacturers) from entering and/or competing effectively in the EndoWrist Repair and Replacement Aftermarket. For instance, in addition to the use counter, Intuitive requires that any surgical instrument attached to the da Vinci have a serial number generated by Intuitive, which Intuitive does not provide to third parties. Because surgical instruments are necessary to perform surgery, Intuitive's design means that customers must purchase EndoWrists to perform surgeries using the da Vinci. Intuitive's serial number requirement effectively forecloses third parties from manufacturing substitutes for EndoWrists.
- 120. Surgical instrument refurbishment is commonly relied on by hospitals and surgery centers. According to an FDA report from 2018, thousands of firms offered medical device

maintenance,<sup>56</sup> and market experts estimate the global market generates between \$28.97 billion<sup>57</sup> and \$35.3 billion<sup>58</sup> in revenue annually. Not only is this market sizable, it is indispensable to the healthcare industry in this country. According to the FDA, the "continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system," and third party entities "provide high quality, safe, and effective servicing of medical devices." Within the broad medical device maintenance and repair space, the maintenance of surgical instruments is expected to see the highest annual growth rate in coming years, according to one market research service.

121. IRCs possess the ability to service EndoWrists to prolong their use. For example, Rebotix has invested substantial time, resources, and money (millions of dollars) to develop the Rebotix Interceptor, which resets the use counter in at least some EndoWrists. The Interceptor only resets the use count; it does not interfere with any other communications the da Vinci has with the EndoWrist. The safety and functionality of the EndoWrist, including communication between the EndoWrist and the da Vinci, are therefore not disturbed. Even in its hobbled state, caused by Intuitive's iron grip, Rebotix provides hospitals with savings of approximately 40% on their EndoWrist expenses. However, as discussed below, *see* § A.3.c, because of anticompetitive

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<sup>&</sup>lt;sup>56</sup> FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), at 19, available at <a href="https://www.fda.gov/media/113431/download">https://www.fda.gov/media/113431/download</a> (last visited on September 10, 2021).

https://www.marketsandmarkets.com/Market-Reports/medical-equipment-maintenance-market-69695102.html (last visited on September 10, 2021).

 $<sup>^{58}</sup>$  <u>https://www.grandviewresearch.com/industry-analysis/medical-equipment-maintenance-market</u> (last visited on September 10, 2021).

<sup>&</sup>lt;sup>59</sup> FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), at i, available at <a href="https://www.fda.gov/media/113431/download">https://www.fda.gov/media/113431/download</a> (last visited on September 10, 2021).

countermeasures Intuitive employs, the Interceptor has limited applicability as it does not work with the newer Xi model.

- 122. As discussed above, *see*, *e.g.*, paragraphs 77-89, Restore specializes in servicing da Vincis and EndoWrists, and hires da Vinci-certified field service engineers with prior training and experience at Intuitive. Restore has been servicing EndoWrists since 2018. While Restore can reset the use counter on EndoWrists for the Si robot, it pays a large licensing fee for the technology to do so. Restore passes these costs on to its customers in the form of at least 20% higher service fees. Still, Restore offers repair (including use-counter reset) rates that are at least 25% on average below the replacement EndoWrist prices offered by Intuitive. Like Rebotix, and again, because of anticompetitive countermeasures taken by Intuitive, Restore cannot reset the use counter for other da Vinci models, including the X and Xi robots. But for the anticompetitive conduct of Intuitive, Restore would be able to offer even lower repair rates and repair services on many more EndoWrists.
- 123. SIS is a veteran of the medical device maintenance industry that recently has made efforts to enter the EndoWrist Repair and Replacement Aftermarket. SIS has 50 years of experience servicing surgical instruments and equipment, ranging from simple devices such as forceps and scalpels to complex electromechanical devices such as flexible video endoscopes, powered orthopedic devices, and surgical video systems. In recent years, SIS created a program for the inspection and repair of EndoWrists. SIS's repair procedures include an initial disassembly and inspection, checking the mechanical operation and integrity of all mechanical components; an electrical integrity check to confirm electrical insulation, cleaning, sharpening, or alignment of the instrument tip; and a series of tests to confirm that all the movements of the instrument tip are within original specifications. SIS also sets the use counter to a value corresponding to the initial setting of a new EndoWrist. These procedures are similar to

procedures that SIS has performed for decades on dozens of types of surgical instruments and medical devices of similar or greater complexity.

- 124. SIS states that it has the personnel, facilities, equipment, and experience to service at least 1,500 EndoWrists per month to prolong their use. In fact, SIS states it has already serviced and repaired EndoWrists that have since been used successfully and without incident in da Vinci surgeries. SIS also claims that independent testing shows that instruments serviced by SIS are suitable for at least 50 uses.
- 125. SIS's initial foray into the EndoWrist Repair and Replacement Aftermarket was successful. Although SIS did not contact potential customers until 2019, by 2020 SIS expected tens of millions of dollars in sales for the repair of EndoWrists. SIS had obtained and was in the process of repairing EndoWrists from some of its initial customers before Intuitive began pressuring those customers to abandon their efforts to secure the cost savings offered by SIS.
- 126. Despite the IRCs' efforts described above, Intuitive has maintained a market share in the EndoWrist Repair and Replacement Aftermarket of well over 95% for nearly 20 years.
  - b. The Geographic Market for the EndoWrist Repair and Replacement Aftermarket
- 127. Intuitive is the sole manufacturer of EndoWrists worldwide and is the only seller of EndoWrists in the U.S. U.S.-based IRCs such as Restore, Rebotix, Revanix, and SIS have the capability to service EndoWrists throughout the U.S.
- 128. EndoWrists are the only surgical instruments that are compatible with and FDA-approved for use with the da Vinci, making them the only surgical instruments available for use with the da Vinci in the U.S.
- 129. U.S. hospitals are thus unable to buy EndoWrists, or potentially substitutable instruments, from suppliers in other countries, even though Intuitive sets its EndoWrist prices above competitive levels.

#### Intuitive's Suppression of Competition in the EndoWrist Repair and c. **Replacement Aftermarket**

- Intuitive contractually ties its provision of da Vincis, and service of the robot, to a 130. customer's agreement to purchase new EndoWrists from Intuitive as the exclusive means to continue using the customer's da Vinci (i) if and when the customer's EndoWrists fall out of perfect condition and, in any event, (ii) once the customer's EndoWrists reach their arbitrary use limits. Intuitive generally includes these contractual provisions in the Sales Agreements for its da Vinci. These provisions combine to restrict competition in the EndoWrist Repair and Replacement Aftermarket and thereby dramatically increase the number and price of new EndoWrists Intuitive's customers must buy from Intuitive.
- 131. Intuitive's Sales Agreements for the da Vinci expressly prohibit its customers from performing repairs on EndoWrists—for example, sharpening the scissors or aligning the graspers. In other words, customers must commit to purchasing replacement EndoWrists from Intuitive (rather than EndoWrist service from third parties). The service agreement for the da Vinci—which often is combined with the Sales Agreements—similarly provides that if any third party repairs the EndoWrists, Intuitive no longer is obligated to service the da Vinci itself. In addition, under the service agreement, any third-party service on an EndoWrist voids Intuitive's one-year warranty not just on that EndoWrist but on the da Vinci as well.
- Intuitive's Sales Agreements further tie the purchase or lease of a da Vinci to the 132. "maximum number of uses" requirement for EndoWrists. Those Sales Agreements provide that the customer "purchases" any instruments for use with the da Vinci from Intuitive, and require that the customer use those instruments only for the "maximum number of uses" set forth in the instrument catalog. These provisions require customers whose EndoWrists have reached their "maximum number of uses" to purchase new EndoWrists—regardless of whether the used EndoWrists are in perfect condition or could be returned to such condition through routine

arbitrarily set by Intuitive.

repairs. During the relevant time period, the most common use limit for EndoWrists was ten. But the safe and usable life of EndoWrists far exceeds the maximum number of uses designated by Intuitive. For example, forceps that are periodically inspected and, if necessary, aligned or adjusted can still be in perfect condition after well over 100 uses. But, because of Intuitive's Sales Agreements, hospitals are contractually obligated to buy far more (ten to twenty times as many) EndoWrists from Intuitive than they actually would need if the restrictive tying clause were eliminated. The clause prevents hospitals from using the services of third-party service

Intuitive has also acted with the clear intent to limit competition in the EndoWrist Repair and Replacement Aftermarket through its design of the EndoWrist itself, including features solely intended to exclude competitors from the EndoWrist Repair and Replacement Aftermarket. These features allow Intuitive to maintain its monopoly and cause Intuitive's customers to pay exorbitant sums to Intuitive for brand new EndoWrists they do not yet need.

providers (such as the IRCs) to safely extend the life of their EndoWrists beyond the use limits

For example, as discussed above, in order to enforce the "maximum number of 134. uses" requirement for EndoWrists, Intuitive includes a programmed memory chip in each EndoWrist that counts the number of times the EndoWrist is attached to a da Vinci, and then renders the EndoWrist non-functional after an Intuitive-specified number of uses. After the memory chip reaches the count determined by Intuitive, the memory chip is wiped, preventing the EndoWrist from communicating with the da Vinci and rendering the instrument inoperable. This memory-wipe causes Intuitive customers to discard EndoWrists and purchase new ones after a given number of uses—usually ten—even when the EndoWrists are maintained at or better than their original levels of safety and effectiveness. Conceding that the design of the useactivated chip memory-wiper is intended as an enforcement mechanism for its contractual ties,

Intuitive has stated in a filing with this Court that "the instruments were always designed to ensure compliance with [Intuitive]'s usage limits." Intuitive's Reply Mem. of Law in Support of Its Mot. To Dismiss (Sept. 3, 2021) (ECF No. 57), at 5, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC.

- 135. The use-triggered memory-wipe of EndoWrists is not based on considerations of safety or effectiveness. All components of the EndoWrists are medical-grade materials that are capable of many times the number of uses permitted by Intuitive. The memory chip does not monitor the safety or durability of EndoWrists—the chip does not, for example, determine whether components of the EndoWrist have become unresponsive to requested movement. Instead, the memory chip tracks only the number of times the EndoWrist is attached to a da Vinci robot arm. Through the memory-wipe function of this memory chip, Intuitive causes EndoWrists to become inoperable long before they otherwise would wear out. This planned obsolescence severely inhibits competition for EndoWrist repairs and enables Intuitive to extract additional profits from its customers, who as a consequence must buy additional EndoWrists at supracompetitive prices.
- 136. The use limits are not based on any FDA or other regulatory requirement. As set forth above, Intuitive's premarket notifications to the FDA for the EndoWrists represented to the FDA that they were "essentially identical" to their precursor traditional laparoscopic instruments, which did not include any use limits, and which can safely be used for more than 100 surgeries. The FDA approved the EndoWrists on that basis.
- 137. Intuitive's standard contracts and instrument catalogs do not refer to any regulatory requirement mandating use limits.
- 138. The use limits are not based on any clinical or scientific determination of the useful life of the instruments. Intuitive has not released to the public, nor does it provide to its

customers, any clinical data that supports its EndoWrist use limits. In addition, analogous surgical instruments used by other surgical robots do not have use limits. For example, the TransEnterix Senhance robot discussed above uses surgical instruments that are substantially the same as Intuitive's EndoWrists, but do not have arbitrary, contractually- or technologicallyimposed use limits.

- 139. Moreover, doctors and hospitals who have used EndoWrists beyond their programmed use limits (i.e., after being inspected and repaired by IRCs who also reset the memory chip's use counter) report that the EndoWrists perform as well as when they were new.
- 140. Intuitive has in fact admitted that the artificially limited lifespan of EndoWrists is intended to boost Intuitive's recurring revenue. During a 2005 presentation and Q&A session, Lonnie Smith, then Intuitive's CEO, discussed the ten-use limit on EndoWrists and touted the resulting recurring revenue streams it generated for Intuitive. Asked what made the EndoWrists usable only ten times, Smith responded that "part of it was, is to make it economically feasible as a company, I mean viable as a company because one of our competitors, our competitor, the one that failed, had very little recurring revenue stream, almost none . . . . And so it was part of our business model as well."60 Intuitive has similarly called its da Vinci business model a "razor/razor blade" model, with recurring revenues from replacement EndoWrists being a key revenue driver, similar to how razor manufacturers generate far greater revenue on replacement blades than on the razors themselves. In sharp contrast to razor manufacturers, though, Intuitive possesses monopoly power in the market for minimally invasive surgical robots and has leveraged that monopoly power in the primary market to insulate itself from competition in the

<sup>60</sup> Lonnie Smith, From Start-up to Market Dominance in the Field of Surgical Robotics, Entrepreneurial Thought Leaders (2005), https://ecorner.stanford.edu/podcasts/from-start-up-tomarket-dominance-in-the-field-of-surgical-robotics/ (last visited on September 10, 2021).

complementary consumables aftermarket. And, as detailed above, Intuitive has been successful in executing on this strategy: thanks to its exclusionary conduct, a growing majority of Intuitive's revenue (today, close to 60%) is derived from sales of the comparatively simple EndoWrists.

- 141. Even though IRCs such as SIS, Restore, and Rebotix have the expertise to enter the EndoWrist Repair and Replacement Aftermarket, Intuitive has designed both the da Vinci and EndoWrists to inhibit the ability of these IRCs to compete in that Aftermarket.
- 142. Intuitive's intentional EndoWrist design choice to use a memory-wipe triggered by an Intuitive-set number of uses has caused SIS, Restore, and Rebotix to invest significant time and resources to develop various means to attempt to overcome the anticompetitive barriers.

  Intuitive had built and compete in the EndoWrist Repair and Replacement Aftermarket.
- technological ties in EndoWrists compatible with its newer X and Xi model da Vincis, and is in the process of using its monopoly power in the market for minimally invasive surgical robots and the da Vinci service aftermarket to cause customers to transition to the newer models. The solutions discovered by Restore and Rebotix to overcome the anticompetitive barriers Intuitive had built work only for EndoWrists used with the older da Vinci models (the S and Si models), not the newer, X and Xi models. Intuitive invested substantial resources and excessive efforts to re-design the memory chip installed in EndoWrists for the X and Xi models solely to prevent any third parties (including SIS, Restore and Rebotix) from servicing EndoWrists, to the detriment of Class members. There is no technical or safety justification for these changes. The anticompetitive intent behind these changes is further demonstrated by the fact that Intuitive had received reports by or before 2012—well before the launch of the Xi in 2014 or the X in 2017—

that hospitals were circumventing the memory-wiper on EndoWrists and using them beyond Intuitive's arbitrary preprogrammed use limits.

- 144. Intuitive has further withdrawn its support for certain S and Si instruments and announced, in writing, its intention to discontinue production of all S and Si instruments and technical support for the da Vinci S and Si models in 2023. In this way, Intuitive is forcing its customers to switch to the da Vinci X and Xi models. Intuitive also raised the prices for some EndoWrists with the introduction of the X and Xi models.
- 145. As discussed above, Intuitive has unilaterally changed functional counter values for certain EndoWrists by, among other things, changing the IFU for EndoWrists to cause early replacement, even if the (already arbitrary) use limit has not been reached. For instance, Intuitive issued an IFU for EndoWrists setting a maximum number of autoclave cycles. Because of the way that da Vinci surgeries are prepped and performed, EndoWrists often have to undergo an autoclave cycle even if not actually attached to a robot during surgery. The specified limit on autoclave cycles is extremely low compared to comparable devices made of similar medical grade materials. These unilateral changes substantially increase the per-surgery cost of EndoWrists to hospitals, and Intuitive's supracompetitive EndoWrist profits, without prior notice to hospitals. And, because Intuitive does not provide hospitals any option for repair of the EndoWrist after the maximum number of autoclave cycles or use limit has been reached, Intuitive's unilateral changes to the IFU narrow the window in which IRCs may repair EndoWrists before the memory-wipe renders them inoperable.
- 146. Intuitive actively monitors the EndoWrist Repair and Replacement Aftermarket to ensure its monopoly remains uninterrupted and its customers continue to buy EndoWrists they would not yet need but for Intuitive's anticompetitive behavior. If a customer or IRC services an

EndoWrist so that it can be used beyond Intuitive's arbitrarily set maximum use limit, Intuitive sends a letter demanding that they cease and desist from resetting the memory chip.

- 147. For example, when hospitals hire IRCs to repair their EndoWrists rather than purchase new ones, Intuitive representatives threaten to withhold maintenance services from the hospital should it continue to make such repairs rather than purchase more EndoWrists.

  Similarly, when a hospital uses an EndoWrist beyond the limit set by Intuitive, Intuitive threatens to withhold maintenance services for the hospital's da Vincis.
- Intuitive's anticompetitive conduct, hospitals are dependent on robot maintenance services for the continued operation of their da Vincis. The services include "provid[ing] and install[ing] Software upgrades"; "replac[ing] defective malfunctioning System parts"; and "replac[ing] and install[ing] Software, Hardware, and mechanical parts for safety." Each of these services can be obtained only from Intuitive. And if these services are not provided—e.g., if a malfunctioning part is not replaced or the Software is not up-to-date—the da Vinci will display a "NEEDS SERVICE" warning message on the display panel. Doctors will not perform a surgery with a machine indicating that it "NEEDS SERVICE." Nor will patients allow themselves to be operated upon by a machine that "NEEDS SERVICE." Accordingly, when service is needed, the da Vinci is effectively rendered useless until service is provided. Hospitals cannot afford to have useless da Vincis. Da Vincis are large capital investments, and ongoing da Vinci surgeries are necessary to recoup that investment. Functional da Vincis also are necessary to maintain the goodwill of the doctors and patients who have scheduled minimally invasive robotic surgeries.
- 149. Intuitive has also attempted to scare potential competitors out of the EndoWrist Repair and Replacement Aftermarket. On or about February 12, 2019, Intuitive sent a cease-and-desist letter to Restore, demanding that it "immediately cease and desist" from "contacting

Intuitive's customers to offer service related to Intuitive's products" and resetting EndoWrist use counters. Intuitive also has sent letters to Rebotix's customers, threatening to withhold necessary contractual maintenance if a hospital uses Rebotix's EndoWrist repair services. This would render the da Vinci useless. Further, after learning that its customers had entered into service contracts with SIS, Intuitive sent letters threatening to render the surgical robot inoperable and falsely claiming that using repaired EndoWrists would violate FDA requirements and intellectual property rights. SIS alleges that as a result of Intuitive's threats, all of its customers backed out of their service agreements with SIS.

- 150. Intuitive's anticompetitive conduct enables it to charge its customers supracompetitive prices that are independent of and far exceed the cost of EndoWrists. For example, as previously noted, Restore claims that Intuitive charges at least 25% higher prices on average for EndoWrist replacement compared with EndoWrist repairs by IRCs.
- 151. As a result of its exclusionary scheme, Intuitive can and does charge supracompetitive prices to replace EndoWrists at significantly higher costs than offered by IRCs to service EndoWrists for prolonged use.

## B. Intuitive's Anticompetitive Conduct Injured Plaintiffs and the Proposed Class.

152. The da Vinci repair services and replacement of EndoWrists provided by Intuitive are substitutable with the da Vinci and EndoWrist repair services provided (or that could be provided) by IRCs, such that being able to hire IRCs could save hospitals a significant amount of money. However, due to the exclusionary service and EndoWrist replacement commitments Intuitive tied and ties to the purchase or lease of the da Vinci, these substitute services are typically not a viable option for hospitals. Hospitals, therefore, are driven to pay higher prices to obtain da Vinci service and (more frequent) EndoWrist replacements from Intuitive.

- EndoWrists are the only instruments that are FDA-approved to work with the da 153. Vinci. Within its Sales Agreements for the da Vinci, Intuitive ties the purchase or lease of the robot to for the purchase of EndoWrists. Thus, customers have no choice but to accept Intuitive's restrictive terms and supracompetitive prices for the replacement of EndoWrists. Similarly, because Intuitive ties the purchase or lease of the da Vinci to the purchase of a da Vinci service agreement requiring all servicing of the da Vinci be performed by Intuitive or its agents, customers thereby accept Intuitive's restrictive terms despite the supracompetitive pricing that flows from Intuitive's anticompetitive scheme.
- 154. Intuitive's tying and exclusive dealing scheme ensures high recurring revenues because it causes Intuitive's customers to constantly purchase EndoWrist instruments after as few as ten uses at a significant and unnecessary cost, instead of having them serviced for prolonged use, and to have to pay Intuitive inflated recurring fees for da Vinci service.
- 155. Restore claims to (a) offer service of the da Vinci at effective rates of less than 50% of the effective rates offered by Intuitive, and (b) repair EndoWrists at least 25% on average below replacement rates offered by Intuitive. SIS claims that a hospital would save 55-70% by having its EndoWrists serviced by SIS rather than purchasing replacement EndoWrists from Intuitive. Similarly, Rebotix claims to provide significant savings to hospitals on EndoWrist expenses, while providing as much safety and efficacy as Intuitive. And according to Great Lakes, repairing EndoWrists could save hospitals more than \$100,000 per robot, per year. 61 With a current installed base of approximately 3,720 da Vincis in the U.S., this suggests a total savings of at least \$372 million per year on EndoWrists alone if EndoWrists were repaired by IRCs instead of having to be replaced by Intuitive. Savings likely would be even greater, for both da

<sup>61</sup> https://www.greatlakesrobotics.net/sales

Vinci service and EndoWrist repairs, through IRCs' realization of economies of scale if they were not stifled by Intuitive's scheme.

- In the but-for world, absent Intuitive's unlawful restraints, Intuitive would need to 156. compete on price to protect an erosion of its market share in response to IRCs' lower prices. For da Vinci service, this would mean lowering the prices charged by Intuitive for such service. For EndoWrists, this would mean reducing Intuitive's own prices for replacement EndoWrists, increasing the number of times an EndoWrist can be used, or both. The downward pressure on price that would result from unfettered competition between Intuitive and its IRC rivals would inure to the benefit of all direct purchasers in the market, whether they purchased from Intuitive or an IRC rival (or both).
- According to a systematic cost assessment made on robotics in general surgery: 157. "Nowadays, the only commercially available robotic equipment (da Vinci®, Intuitive Surgical Inc.; CA, USA) is characterized by elevated cost, including the cost of acquisition, training, and equipment-instrument cost, as well as that of maintenance of the robotic system (with an annual service contract, over 100,000 US dollars)."<sup>62</sup>
- By tying the purchase or lease of the da Vinci to both the service of the da Vinci 158. and the commitment to purchase replacement EndoWrists from Intuitive rather than servicing already-owned EndoWrists, Intuitive captures nearly 100% of the U.S. da Vinci service aftermarket and EndoWrist Repair and Replacement Aftermarket. In its annual reports, Intuitive repeatedly notes that IRCs may emerge and compete with Intuitive on price or offerings, and Intuitive's failure to compete successfully with these IRCs may cause its revenues to suffer. This

Assessment. Journal of Minimal Access Surgery, 13(4), 243–255. Https://Doi.Org/10.4103/0972-9941.195565

<sup>&</sup>lt;sup>62</sup> Gkegkes, I. D., Mamais, I. A., & Iavazzo, C. (2017). Robotics in General Surgery: A Systematic Cost

acknowledgement from Intuitive demonstrates that absent Intuitive's anticompetitive conduct, not only would the hospitals that purchased or leased da Vincis from Intuitive have cheaper alternatives from IRCs in terms of servicing the da Vinci and/or EndoWrists, but Intuitive would charge lower prices (and/or, with respect to EndoWrists, increase the maximum number of uses allowed) to better compete with these IRCs.

- 159. The exclusionary scheme has the effect of driving the majority of Intuitive's annual revenues. First, demand for da Vinci service and EndoWrist replacement or repair is largely derived from demand for da Vincis. So, by purchasing a da Vinci to attract more patients and skilled surgeons to their facilities, hospitals are automatically locked into the Intuitivecontrolled da Vinci service aftermarket and EndoWrist Repair and Replacement Aftermarket.
- 160. In fact, in its 2019 10-K, Intuitive reported 57% of its U.S. revenue was attributable to instruments and accessories, and 16% was attributable to service contracts. 63 In the U.S., Intuitive reported (a) \$508 million in revenue from service contracts, and (b) \$1.79 billion in revenue from instruments and accessories. <sup>64</sup> Furthermore, Intuitive's net income for 2019 in the U.S. was 31% of total revenue. 65 This greatly exceeds the average profit margin of 8.5% in the medical equipment repair & maintenance industry. 66
- 161. There are no legitimate business, safety, or efficiency justifications for Intuitive's anticompetitive scheme, which was employed for the sole purpose of eliminating competition in the da Vinci service aftermarket and EndoWrist Repair and Replacement Aftermarket, thereby

<sup>&</sup>lt;sup>63</sup> Intuitive (Form 10-K), at 56 (Feb. 7, 2020).

<sup>&</sup>lt;sup>64</sup> *Id.* at 87.

<sup>&</sup>lt;sup>65</sup> *Id*. at 45.

<sup>66</sup> Jack Curran, "Medical Equipment Repair & Maintenance Services," IBIS World, June 2020, at 7.

causing Plaintiffs and the Class to pay significantly more than they would have in a competitive market for these services.

162. Intuitive has engaged in a continuing scheme to monopolize the aftermarket for da Vinci service and the EndoWrist Repair and Replacement Aftermarket. In doing so, Intuitive has committed continuing overt acts in furtherance of that scheme. These acts include tying the purchase or lease of a da Vinci robot to the purchase of da Vinci service from Intuitive; tying da Vinci parts to the purchase of da Vinci service from Intuitive; requiring customers to enter into multi-year, exclusive da Vinci service agreements with Intuitive; designing the da Vinci to work only with parts with Intuitive serial numbers and refusing to provide such serial numbers to any third parties; restricting access to software necessary to maintain the da Vinci; tying the purchase or lease of a da Vinci to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached; tying the ongoing maintenance of the da Vinci to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached; requiring da Vinci purchasers not to repair their EndoWrists through IRCs; selling replacement EndoWrists with use-limit-triggered memory-wipers and at prices inflated by the scheme; forcing obsolescence of the S and Si da Vinci models and designing Xi and X model EndoWrists to thwart the use counter reset workarounds developed by IRCs; threatening and coercing IRCs such as SIS, Restore, and Rebotix; and threatening and coercing hospitals and other da Vinci robot purchasers who have expressed an interest in using IRCs to repair da Vinci robots or EndoWrists or using EndoWrists longer than the use limits arbitrarily set by Intuitive.

#### **CLASS ALLEGATIONS**

163. Plaintiffs bring this action on behalf of themselves and on behalf of a class (the "Class") consisting of all entities that purchased da Vinci service and/or EndoWrists from

Intuitive in the United States at any time from May 21, 2017 to the present (the "Class Period"). Excluded from the Class are Defendant, its officers, subsidiaries, and affiliates, and all government entities.

- 164. Plaintiffs seek class certification pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure.
- 165. **Numerosity.** Hundreds of hospitals, trauma centers, and/or clinics have purchased da Vinci service and EndoWrists during the Class Period pursuant to Intuitive contracts that tied the purchase or lease of da Vincis to aftermarket sales of service and EndoWrist replacements (and also tied da Vinci service to EndoWrist replacements). Thus, there are numerous Class members and joinder is impracticable. The Class members are identifiable from information and records that are required by law to be maintained by Defendant.
- 166. **Typicality.** Plaintiffs' claims are typical of the claims of the other members of the proposed Class. Plaintiffs and members of the proposed Class purchased da Vinci service and/or EndoWrist replacements directly from Defendant during the Class Period at supracompetitive prices resulting from Defendant's unlawful actions. Plaintiffs and members of the Class have sustained damages in that they paid inflated prices for the service and repair of da Vincis and replacement of EndoWrists during the Class Period due to Defendant's conduct in violation of federal law.
- 167. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect and represent the interests of the proposed Class. The interests of the Plaintiffs are not antagonistic to those of the proposed Class. In addition, Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action, antitrust, and consumer protection litigation.

- 168. **Ascertainability.** Plaintiffs have defined the Class so that Class members can be identified using objective criteria, i.e., entities that purchased da Vinci service and/or EndoWrists directly from Intuitive during the Class Period. Defendant's data can identify all Class members.
- 169. **Commonality and Predominance**. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual members.
  - 170. Questions of law and fact common to the Class include without limitation:
    - i. Whether Defendant's conduct constitutes illegal tying under Section 1 of the Sherman Act;
    - ii. Whether Defendant's conduct constitutes illegal exclusive dealing under Section 1 of the Sherman Act;
    - iii. Whether Defendant's conduct constitutes illegal monopolization under Section 2 of the Sherman Act;
    - iv. Whether Defendant abused its monopoly power in the U.S. minimally invasive surgical robot market in order to gain a competitive advantage in the aftermarkets to service and repair da Vincis and repair or replace EndoWrists in violation of Sections 1 and 2 of the Sherman Act:
    - v. Whether Defendant's conduct had the effect of substantially lessening competition in the (1) da Vinci Service; and (2) EndoWrist Repair and Replacement Aftermarkets;
    - vi. Whether Defendant's unlawful conduct caused Plaintiffs and the proposed Class to pay more (1) for da Vinci service, and (2) to service, repair, and/or replace EndoWrists than they otherwise would have paid;
    - vii. The appropriate measure of damages incurred by Plaintiffs and the proposed Class;
    - viii. Whether Plaintiffs and other Class members are entitled to injunctive relief; and
    - ix. The appropriate injunction needed to restore competition in the aftermarkets.
- 171. **Superiority.** A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable.

The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the courts and Defendant, and would create a risk of inconsistent or varying adjudications of the questions of law and fact common to the Class. A class action, on the other hand, would achieve substantial economies of time, effort, and expense, and would assure uniformity of decision as to persons similarly situated without sacrificing procedural fairness or bringing about other undesirable results.

172. The interest of members of the Class in individually controlling the prosecution of separate actions is theoretical rather than practical. The Class has a high degree of cohesion, and prosecution of the action through a representative or representatives would be unobjectionable. The amounts at stake for Class members, while substantial in the aggregate, are not great enough individually to enable them to maintain separate suits against Defendant. Plaintiffs do not anticipate any difficulty in the management of this action as a class action.

#### **CAUSES OF ACTION**

## COUNT I – TYING (DA VINCI SERVICE AFTERMARKET)

- 173. Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.
- 174. Intuitive has engaged in an unlawful tying arrangement in unreasonable restraint of trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This illegal scheme tied the purchase or lease of the da Vinci to da Vinci service.
- 175. Minimally invasive surgical robots and da Vinci service are separate products that are sold or leased in separate markets from one another.

- 176. At all times relevant to this action, Intuitive has maintained substantial economic power in the minimally invasive surgical robot market. Intuitive's tying arrangement has had anticompetitive effects in the domestic da Vinci service aftermarket.
- Intuitive's tying scheme had no legitimate safety, efficiency, or business purpose. 177. It achieved no legitimate efficiency benefits and had the anticompetitive effect of foreclosing competition in the aftermarket to service the da Vinci, such that Plaintiffs and the Class could obtain these services only from Intuitive.
- A substantial amount of interstate commerce was affected by Intuitive's tying 178. scheme. Intuitive reported \$508.4 million revenues from service contracts and \$1.79 billion revenues from instruments and accessories in 2019 alone. These amounts accounted for 73% of Intuitive's U.S. revenues in 2019.
- As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase da Vinci service at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

# **COUNT II – EXCLUSIVE DEALING** (DA VINCI SERVICE AFTERMARKET)

- Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as 180. though fully set forth herein.
- 181. Intuitive has dominant economic power in the domestic market for minimally invasive surgical robots, the domestic da Vinci service aftermarket, and the domestic EndoWrist Repair and Replacement Aftermarket. Intuitive has taken measures and entered into agreements with its customers that require the customers to purchase service for the da Vinci from Intuitive exclusively. These agreements are unreasonable restraints of trade that have foreclosed

competition in the domestic da Vinci service aftermarket, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

182. As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase da Vinci service at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

# COUNT III – MONOPOLIZATION (DA VINCI SERVICE AFTERMARKET)

- 183. Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.
- 184. Intuitive has willfully obtained and willfully maintains monopoly power in the domestic da Vinci service aftermarket in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive maintains at least a 98% market share by excluding competitors. Intuitive's exclusionary tactics include tying the purchase or lease of the da Vinci to the purchase of service from Intuitive; including contractual provisions in sales and servicing agreements prohibiting customers from having their da Vincis serviced by third parties; designing da Vincis to inhibit the ability of IRCs to perform maintenance on them; sending cease-and-desist letters when customers attempt to use IRCs to service da Vincis; and threatening customers who attempt to repair their da Vincis with IRCs.
- 185. As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase da Vinci service at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

## **COUNT IV – TYING** (ENDOWRIST REPAIR AND REPLACEMENT AFTERMARKET)

- 186. Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.
- 187. Intuitive has dominant economic power in the domestic market for minimally invasive surgical robots. Intuitive has tied the purchase or lease of the da Vinci and purchase of da Vinci service to customers purchasing replacement EndoWrists from Intuitive instead of repairing the EndoWrists that the customers already have, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.
- 188. Minimally invasive surgical robots and the service, repair, and replacement of EndoWrists are separate products that are sold or leased in separate markets from one another.
- 189. Intuitive's tying scheme had no legitimate safety, efficiency, or business purpose. It achieved no legitimate efficiency benefits and had the anticompetitive effect of foreclosing competition in the market to service, repair, and replace EndoWrists such that Plaintiffs and the Class could obtain these services only from Intuitive.
- A substantial amount of interstate commerce was affected by Intuitive's tying 190. scheme. Just in 2019, Intuitive's total revenues from instruments and accessories, including EndoWrists, exceeded \$1.79 billion, and Intuitive reported \$508 million revenues from service contracts. These amounts accounted for 73% of Intuitive's U.S. revenues in 2019.
- 191. As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase EndoWrists unnecessarily at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

## COUNT V – EXCLUSIVE DEALING (ENDOWRIST REPAIR AND REPLACEMENT AFTERMARKET)

- 192. Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.
- 193. Intuitive has dominant economic power in the domestic market for minimally invasive surgical robots, the domestic da Vinci service aftermarket, and the domestic EndoWrist Repair and Replacement Aftermarket. Intuitive has taken measures and entered into agreements with its customers that require the customers to service and replace their EndoWrist instruments with Intuitive exclusively. These agreements are unreasonable restraints of trade that have foreclosed competition in the domestic EndoWrist Repair and Replacement Aftermarket, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.
- 194. As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase EndoWrists unnecessarily at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

## COUNT VI – MONOPOLIZATION (ENDOWRIST REPAIR AND REPLACEMENT AFTERMARKET)

- 195. Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.
- 196. Intuitive has willfully obtained and willfully maintains monopoly power in the domestic EndoWrist Repair and Replacement Aftermarket in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive maintains at least a 98% market share by excluding competitors. Intuitive's exclusionary tactics include tying the purchase or lease of da Vincis to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached, tying the ongoing maintenance of da Vincis to the

commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached, prohibiting customers from having their EndoWrists repaired, sending cease-and-desist letters when customers attempt to repair EndoWrists, threatening customers who attempt to repair EndoWrists, incorporating a memory-wiper into every EndoWrist to require additional EndoWrist purchases instead of repairs, and introducing design changes intended to thwart repair solutions developed by IRCs in response to the memory-wiper.

197. As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase EndoWrists unnecessarily at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class respectfully request the following relief:

- A. Certify the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure, certify Plaintiffs as Class representatives and designate their counsel as counsel for the Class;
  - B. Declare that Defendant's conduct violates Sections 1 and 2 of the Sherman Act;
- C. Award Plaintiffs and the members of the Class damages determined to have been sustained by each of them, trebled as provided by law;
- D. Award Plaintiffs and the members of the Class pre- and post-judgment interest as allowed by law at the highest legal rate from and after the date of service of the complaint—June 17, 2021—in *Larkin v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03825-VC (Doc. No. 1);
- E. Permanently enjoin and restrain Defendant, its affiliates, successors, heirs, transferees, assignees, and officers, directors, partners, agents, and employees thereof, and all other entities or persons acting or claiming to act on their behalf or in concert with them, from in

any manner continuing, maintaining, or renewing the conduct and overcharges alleged herein, or from engaging in any other conduct, conspiracy, combination, or overcharges having a similar purpose or effect;

- F. Award Plaintiffs and the Class their costs of the suit, including attorneys' fees, as provided by law; and
  - G. Grant such other relief as this Court may deem just and proper.

#### **JURY DEMAND**

Plaintiffs and the Class hereby demand trial by jury of all issues properly triable thereby.

DATED: September 10, 2021

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